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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Roland Carlsson et al.

Serial No. 09/734,801

Filed: December 12, 2000

For: "A Method for in Vitro Molecular Evolution of Protein Function"

Bexaminer: Suryaprabha Chunduru

Art Unit: 1637

Molecular Suryaprabha Chunduru

Art Unit: 1637

## DECLARATION OF ROLAND CARLSSON, ANN-CHRISTIN MALMBORG HAGER, CHRISTINA FUREBRING, AND CARL BORREBAECK

We, Roland Carlsson, Ann-Christin Malmborg Hager, Christina Furebring, and Carl Borrebaeck, hereby declare that:

- We are co-inventors of the invention described and claimed in U.S. Patent Application Serial No. 09/734,801 (hereinafter the '801 application).
- 2. We have read and are familiar with the contents of the Official Action dated September 17, 2004 in the '801 application. We note that the Examiner has rejected claims 1-7 under 35 U.S.C. \$103(a) as allegedly unpatentable over U.S. Patent 6,632,610 (hereinafter the '610 patent) in view of U.S. Patent 6,337,186. The purpose of this declaration is to establish that the invention described and claimed in the '801 application (the "subject invention") was completed prior to October 12, 2000, which upon information and belief is the earliest effective filing date of the '610 patent. The present invention was diligently and constructively reduced to practice at least as early as December 12, 2000, the filing date of the instant application.
- Conception of the invention described in the present application is evidenced by copies of pages of a draft of the application, submitted herewith as Exhibits A1

through A21, and copies of drafts of the figures of the application, submitted herewith as Exhibits B1 through B5. Also submitted are Exhibits C1 and C2, which are copies of emails which indicate the dates on which the draft of the application and the drafts of the figures, respectively, were sent by co-inventor Ann-Christin Malmborg Hager to legal counsel. The dates on the emails have been masked for the purpose of this Declaration. The instantly claimed methods are described in Exhibits A1 through A21 and B1 through B5. Specifically, Exhibit A5 teaches a method for generating polynucleotide sequences from a parent polynucleotide sequence, wherein the generated polynucleotide sequences encode for a protein having altered characteristics as compared to the protein encoded for by the parent polynucleotide. method comprises providing plus and minus, single stranded polynucleotides of the parent polynucleotide, digesting the single stranded polynucleotides with an exonuclease thereby generating polynucleotide fragments, contacting the polynucleotide fragments under annealing conditions and optionally adding primers that anneal to the 5' and 3' ends of the parent polynucleotide, and amplifying the polynucleotide fragments that annealed. Exhibits A14 through A21 teach specific reaction conditions employed for performing the described method. Indeed, Exhibits A18 and A19 teach the generation of plus and minus, single stranded polynucleotides of the parent polynucleotide. Exhibits A19 and A20 teach the digestion of the single stranded polynucleotides with the exonuclease BAL 31 and the purification of the resultant polynucleotide fragments. Exhibit A20 also teaches the assembly of the generated fragment by PCR amplification. As indicated at the bottom of Exhibit A20, the resultant PCR product, when cleaved with certain restriction enzymes, produced a "cleavage product of about 750 bp" which "corresponds well with the expected size."

- 4. We were in possession of the invention claimed in the '801 application at least as early as October 12, 2000, which upon information and belief is the earliest effective filing date of the '610 patent. The invention was conceived of and reduced to practice in Sweden, a WTO member country.
- 5. We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the above-referenced application or any patent issued thereon.

| 04/2/9<br>Date<br>04/2/0<br>Date | Roland Carlsson  Ann-Christin Malmborg Hager |
|----------------------------------|--|
| 041210<br>Date                   | Christina Furebring                          |
| 04-12-10<br>Date                 | Carl Borrebaeck                              |